



PHARM DOCS13-PATPAT 2003/APP/1241-03 2003/10/26/1241 Declaration Garcia-Giralt.doc

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Eduardo M. Lasalvia-Prisco

Serial No.: 10/607,358

Filing Date: June 26, 2003

For: A METHOD AND COMPOSITION TO ELICIT AN EFFECTIVE AUTOLOGOUS  
ANTITUMORAL IMMUNE RESPONSE IN A PATIENT

Confirmation No. 6124

Customer No. 04219

Group Art Unit 1643

Sang, Hong, Examiner

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

DECLARATION OF DR. EMILIO GARCIA-GIRALT

I, Dr. Emilio Garcia-Giralt, declare as follows:

1. That I am a Medical Doctor and Oncologist licensed in France, and that through my extensive practice I have gained a significant level of expertise in the field of oncology.

2. That attached hereto is a true and accurate copy of my Curriculum Vitae which includes, among other things, a listing of awards and distinctions I have received, technical and scientific meetings in which I have been an active participant, a summary of my professional activity and clinical practice, as well as a list of some of the scientific publications which I

FROM: DOCS\1-PAT\PAT 2003\APF\1241-2 Pharma B\305\1241 Declaration Garcia-Girelli-300

authored or co-authored that are relevant to the field of oncology.

3. That I am the treating physician for a female patient (hereinafter, "Patient X") who, to the best of my knowledge, was born in France on or about September 17, 1958.

4. That in or about June of 2000, I thoroughly examined Patient X, and based upon my knowledge and expertise in the field, thereafter diagnosed her with breast cancer, with right axillary lymph nodes.

5. That in or about June of 2000, I implemented a standard treatment regimen on Patient X utilizing chemotherapy, including appropriate and sufficient doses of Fluorouracil, Cyclophosphamide, and Adriamycin.

6. That in or about June 2000, I further ordered a mastectomy on Patient X for the surgical removal of the cancerous tissue found in the breast of Patient X, followed by post-surgery treatment regimen utilizing radiotherapy.

7. That in or about June 2003, I diagnosed and verified hepatic metastasis in Patient X, and I implemented a treatment regimen on Patient X utilizing additional and successive chemotherapy regimens at that time, including appropriate and sufficient doses of Taxanes, followed by appropriate and sufficient doses of Navelbine.

8. That in or about July 2004, I implemented a treatment

regimen on Patient X in accordance with the method disclosed in the above-referenced U.S. Patent Application (hereinafter, "the Lasalvia-Prisco Method").

9. That in or about July 2004, the treatment regimen implemented on Patient X included, generally, extracting a blood specimen from Patient X and forming a solution, separating a plasma-cell layer from the solution, diluting the plasma-cell layer in a dilutant forming a plasma-cell solution, cooling and heating the plasma-cell solution, fractioning the plasma-cell solution and forming a plasma-cell fraction, and filtering the plasma-cell fraction prior to administrating the plasma-cell fraction to Patient X.

10. That in or about October 2004, I examined Patient X, subsequent to the treatment with the Lasalvia-Prisco Method, and observed a significant improvement in Patient X relative to the above-referenced breast cancer and hepatic metastasis.

11. That in or about December 2004, after a computerized axial tomography scan, i.e., a "CT Scan" or a "CAT Scan", of Patient X, I did not observe signs, symptoms, or characteristics of breast cancer or hepatic metastasis in Patient X and, in my

expert opinion, Patient X was in remission relative to the breast cancer and hepatic metastasis previously observed and diagnosed.

12. That in about September 2006, Patient X remained in clinical care, and after examining results of a CT Scan and a magnetic resonance imaging ("MRI") of Patient X, I observed no

sign, symptom, or characteristic of breast cancer or hepatic metastasis and, in my expert opinion, I am of the opinion that Patient X has entered complete and total remission relative to the breast cancer and hepatic metastasis previously observed and diagnosed.

13. That to the best of my knowledge, and according to known oncology protocols, the complete and total remission of Patient X relative to the breast cancer and hepatic metastasis is completely unexpected, and evidenced by the fact that the medical dossier of Patient X, i.e., the accumulated records of the medical case history of Patient X, was requested by a French National Committee of Medical Experts that studies oncological cases with remarkable evolution in France.

14. That to the best of my knowledge, the dossier of Patient X is currently under study as a result of the unexpected results, outcome, and evolution of Patient X following treatment in accordance with the Lasalvia-Prisco Method.

15. That I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued

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Dated: October 14, 2006



~~Dr. Emilio Garcia-Giralt~~

DOCTEUR EMILIO GARCIA GIRALT  
73 ONCOLOGIE MEDICALE  
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## **Curriculum Vitae Dr. Emilio Garcia-Giralt**

Name: Emilio Garcia-Giralt  
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France Phone (331) 303-57679  
Email: [egarciagiralt@msn.com](mailto:egarciagiralt@msn.com)

### **EDUCATION**

The educational system in Argentina consists of 6 years of elementary school, four years of High School and 2 years of college introductory to the University or pre-university. To obtain a medical degree 6 years of Medical School are required.

1. Elementary and High School (10 years)
2. College: Biology, Pre-Medical Orientation. (2 years)
3. Medical Doctor. Medical School, University of Buenos Aires

### **POST-GRADUATE STUDIES 1965- 2005**

Oncology

Licensed as Medical Doctor and Oncologist in Paris. France

### **AWARDS, DISTINCTIONS, PARTICIPATION IN TECHNICAL AND SCIENTIFIC MEETINGS**

1. Expert of the French Agency for Health, since July 11, 2002
2. Professor of the University of Catamarca. Argentina
3. American Society of Clinical Oncology
4. Sociedad Argentina de Oncologia
5. Escuela Sudamericana de Oncologia
6. Societe of Cancerologie, France.

## **PROFESSIONAL ACTIVITY-CLINICAL PRACTICE (1968-2006)**

Institut de Cancérologie et d'Immunogénétique. Villejuif. France

Hôpital Gustave Roussi. France

Institut Curie. Paris. France

Centre de Cancérologie Hartmann, Neuilly sur Seine, France

Clinique Saint-Jean de Dieu, 19 rue Oudinot, 75 007 PARIS

## **SCIENTIFIC PUBLICATIONS**

More than 100 Publications in international peer review journals 1968-2005.

Peer review Journals from 1968 to 2006

## **THE MOST RELEVANT SCIENTIFIC PUBLICATIONS**

- ❑ Extraction of an Inhibitor of DNA synthesis from human peripheral blood lymphocytes and bovine spleen. E. Lasalvia, E. García-Giralt, A. Macieira-Coelho. Rev. Europ. Etudes Clin. et Biol. 1970, XV: 789-792
- ❑ Evidence for to lymphocytic chalone. E. García-Giralt, E. Lasalvia, I. Florentin and G. Mathe. Rev. Europ. Etudes Clin. et Biol. 1970, XV: 1012-1015
- ❑ Suppression of Graft-vs. -Host Reaction by to Spleen Extract. E. García - Giralt, VH Morales, E. Lasalvia and G. Mathe. The Journal of Immunology, 1972,109,4:878-880
- ❑ Prevention of Graft versus Host Reaction by incubation of lymphoid cells with to splenic extract (Not Affecting the Repopulation of the Hemopoietic tissue). E. García-Giralt, VH Morales, B. Bizzini and E. Lasalvia. Cell Tissue Kinet, 1973,6:567-571
- ❑ Decreased lymphoid chalone rate in the spleens of lymphoma patients. E. Lasalvia, A. Luquetti, C. Oehninger, and E. García-Giralt. Proc. XV Congress of the International Society of Hematology, 1974
- ❑ Breast Cancer: Updated Vaccination With An Autologous Hemoderivative in Changing Tumor Antigen Library. E. Garcia-Giralt, E. Lasalvia-Prisco, S. Cucchi, J. Vazquez; Proc 40<sup>th</sup> Annual Meeting of ASCO, May 2004, Abs 2594
- ❑ Breast Cancer: Role of Tumor Associated Antigens and Regulatory Cells [CD4+CD25+] as Targets of the Immune Response elicited by an Anti-progressive Autologous Hemoderivative Vaccine. E. Garcia-Giralt, E. Lasalvia-

Prisco, S. Cucchi, J. Vazquez, E. Lasalvia-Galante, W. Golomar. Proc 41<sup>st</sup> Annual Meeting of ASCO, May 2005, Abs. 2589

- Colorectal Cancer: Comparative effects of an Autologous Hemoderivative Vaccine with a CEA vaccine and/or an autologous [CD4+CD25+] vaccine. E. Lasalvia-Prisco, E. Garcia-Giralt, S. Cucchi, J. Vazquez, E. Lasalvia-Galante, W. Golomar. Proc 41<sup>st</sup> Annual Meeting of ASCO, May 2005, Abs. 2596
- Advanced Colon Cancer: Antiprogessive Immunotherapy Using an Autologous Hemoderivative. Eduardo Lasalvia-Prisco, Emilio Garcia-Giralt, Silvia Cucchi, Jesús Vázquez, Eduardo Lasalvia-Galante, Wilson Golomar. IN PRESS to be published in Medical Oncology, Medical Oncology, vol 23, no. 1, 91-104, 2006.
- Advanced Breast Cancer: Antiprogessive Immunotherapy Using a Thermostable Autologous Hemoderivative. Eduardo Lasalvia-Prisco, Emilio Garcia-Giralt, Silvia Cucchi, Jesús Vázquez, Eduardo Lasalvia-Galante, Wilson Golomar. Breast Cancer Research & Treatment. Printed: Online First: [www.springer.com](http://www.springer.com)
- Prostate cancer: autologous immunotherapy optimized by indoleamine- 2,3-dioxygenase (IDO)-inhibitor as immune-tolerance breaker. E. Lasalvia-Prisco, E. Garcia-Giralt, S. Cucchi, J. Larrañaga. Proc. Am Soc Clin Oncol (ASCO), 42nd Annual Meeting 2006: Abs. 12509
- Ovarian cancer: autologous immunotherapy optimized by remote adjuvancy of a silicate -induced granuloma. E. Garcia-Giralt, E. Lasalvia- Prisco, S. Cucchi, E. Lasalvia-Galante, J. Vazquez, W. Golomar, J. P. Vincent. Proc. Am Soc Clin Oncol (ASCO), 42nd Annual Meeting 2006: Abs. 12515

**SPOKEN LANGUAGES**

ENGLISH, SPANISH, FRENCH